

## IS EPA BLOWING ITS OWN SMOKE?

### How Much Science Is Behind Its Tobacco Finding?

By Michael Fumento  
in Los Angeles

"Taken together, the total weight of evidence is conclusive that environmental tobacco smoke increases the risk of lung cancer in nonsmokers."

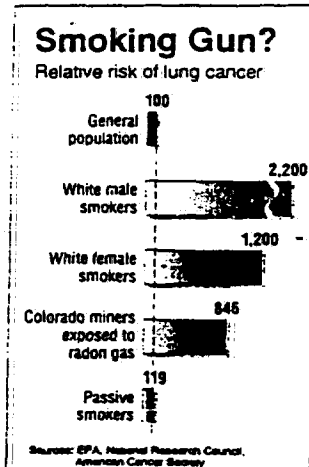
So declared Environmental Protection Agency Administrator William Reilly at a news conference earlier this month, announcing the impending release of an EPA report attributing approximately 3,000 deaths a year to passive smoking, or environmental tobacco smoke.

Yet many in the scientific and medical community say the data the EPA cites does not bear out its conclusion.

While virtually all scientists agree that smoking is unhealthy — both for smokers and those around them — it's the degree to which smoking is unhealthy, and the way the government musters its scientific case, that raises questions.

Some scientists and policy analysts who say they couldn't care less about tobacco company profits or even the rights of smokers are worrying aloud that the EPA report is paving the way for justifying new health-based government regulations and programs without any real science behind them.

Said Bonner Cohen, editor of EPA



Watch based in Chantilly, Va. "It's now open season on whatever contaminant the EPA chooses to label the killer contaminant of the week, with the effect that once again, Americans are going to be stampeded into fearing a substance for reasons which upon close inspection are scientifically indefensible."

Yale University epidemiologist Alvan Feinstein, writing in the journal *Toxicological Pathology*, said he recently heard a prominent leader in epidemiology admit of the EPA's work on passive smoking: "Yes, it's rotten science, but it's in a worthy cause. It will help us to get rid of cigarettes and to become a smoke-free society."

Another critic, Alfred P. Wehner, president of Biomedical and Environmental Consultants Inc., in Richland, Wash., said: "I did work for the EPA in the past and thought of them reasonably well, but when I saw that report, I was really embarrassed. It was a bad document."

One thing both sides agree on is that the direct policy ramifications of the EPA report could be tremendous.

"You can bet your next paycheck that OSHA (the Occupational Safety and Health Administration) will ban all smoking in the workplace," said John Shanahan, the environmental policy analyst at the Heritage Foundation.

Although, in unveiling the report, Reilly expressly referred to cancer in children and in the workplace, the statistical analysis in the EPA report actually ignored the studies that looked for such links.

Rather, the EPA survey is based on 11 American studies of spouses of smokers. The report discussed, but did not put into its statistical analysis, the results of 19 other studies done outside the U.S.

In its analysis of those 11 studies, the EPA found that there was a "statistically significant" difference in the number of lung cancers suffered by non-smoking spouses of smokers, equal to 119 such cancers in nonsmoking spouses of smokers compared to 100 lung cancers in nonsmoking spouses of non-smokers.

This finding of statistical significance allowed it to rank passive smoking as a Class A carcinogen, the highest risk ranking possible.

Statistical significance, while sounding like arcane academic talk, is actually quite important. It is used to account for the possibility that something happened — in this case the 19 additional lung cancers — by chance.

But critics say that, using its own previous statistical standards, the EPA report shows no such significance.

"Frankly, I was embarrassed as a scientist with what they came up with. The main problem was the statistical handling of the data," said Wehner, who headed a panel of scientists and doctors that analyzed the draft version of the EPA report for the tobacco industry.

#### "Meta-Analysis"

One aspect of this problem, say critics, involves the combination of the 11 studies into one big group — what the EPA called a "meta-analysis."

The EPA has never before done this. Critics say such combinations may be valid, but if the studies weren't done in the same way, the results will be like comparing apples and oranges and pears.

Not everyone agrees.

"Meta-analysis is totally fair," said Stanton Glantz of the Institute of Health Policy Studies at the University of California, San Francisco. "I review reports like that for the State of California, and the work the EPA did is absolutely first rate, one of the best pieces of science I've seen about anything."

But Wehner said the study was faulty.

"To get scientifically valid data, there are very strict rules and requirements on how and when you can apply meta-analysis, and virtually all of them were violated in the EPA analysis," he said.

#### "Confidence Intervals"

The 11 studies together actually reflected 10 studies that showed no statistically significant increases in cancer and only one that did. When the EPA says that the weight of 11 studies showed harm from passive smoking, it really meant one positive combined with 10 neutrals.

More important than the use of the meta-analysis, say critics, is the EPA's use, also for the first time, of a less rigorous statistical analysis.

Epidemiologists — those who study disease and accident patterns to establish why they occur — calculate "confidence intervals" to express the likelihood that a result could have happened strictly by chance.

A 95% confidence interval means that there is a 95% possibility that the result didn't happen from chance, or a 5% possibility that it did.

Until the passive smoking report, the EPA has always used a 95% confidence interval, as have most researchers doing epidemiological studies. Indeed, all of the individual ETS studies were published with 95% confidence intervals.

Yet, in its averaging of those ETS studies, the EPA decided to go with a 90% confidence interval.

"That doubles the chance of being wrong," explained James Enstrom, a professor of epidemiology at the University of California, Los Angeles.

Reilly said simply: "With respect to the confidence interval, we have here a 90% confidence level. And that was, in fact, what was recommended to us by the scientific community as appropriate to this data." Repeated calls to the EPA to find out who in the scientific community had done so went unanswered.

#### "Hairsplitting" Factor

Glantz said the criticism of the change in the confidence level is a kind of "hairsplitting" that only professors care about.

Many epidemiologists, however, disagree.

"In most cases, a scientist would never do this sort of thing," Enstrom said. "It's surprising that they would try to get away with it."

The bottom line is that such "hairsplitting" allowed the EPA to come to a totally different conclusion than it would have using its normal method.

It could now declare that the results of the American studies, when lumped together, were "statistically significant," a term of great importance to the medical community. At a 95% confidence



William Reilly

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